

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA**

WHOLE WOMAN'S HEALTH
ALLIANCE, *et al.*,

Plaintiffs,

v.

FOOD AND DRUG ADMIN., *et al.*,

Defendants.

Case No. 3:23-cv-00019-NKM

EMERGENCY MOTION FOR EXTENSION OF TIME

Defendants respectfully move this Court to extend Defendants' time to respond to Plaintiffs' Motion for Preliminary Injunction (ECF No. 8) from May 23, 2023, to June 6, 2023. As set forth herein, good cause exists for this two-week extension, which will not prejudice Plaintiffs. Plaintiffs' counsel has informed undersigned counsel that "Plaintiffs oppose this Motion and believe a hearing date the week of June 5 with Defendants' response due within 14 days of service pursuant to Local Rule 11(c)(1) is appropriate." Because Defendants' current deadline is seven days from now, Defendants respectfully requested expedited consideration of this Motion.

1. Plaintiffs served the United States Attorney's Office with their Complaint and Motion for Preliminary Injunction on May 9, 2023. ECF No. 15. Thus, pursuant to Local Rule 11(c)(1), Defendants' response to the Motion for Preliminary Injunction is due on May 23, 2023.

2. The requested extension to June 6, 2023, is necessary to permit Defendants sufficient time to respond to Plaintiffs' Motion. Plaintiffs' Complaint, exhibits, Motion, and declarations total over 470 pages, and Defendants and their counsel request the additional time to adequately review these materials and prepare a response that can best aid the Court in consideration of Plaintiffs' motion. Moreover, Defendants expect that in addition to opposing Plaintiffs' Motion for Preliminary Injunction, they will move to stay this case pending the resolution of appellate proceedings in *Alliance for Hippocratic Medicine, et al. v. FDA*, discussed below. Granting Defendants their requested extension will permit Defendants sufficient time to simultaneously file their expected Motion to Stay Proceedings.

3. Plaintiffs will not be prejudiced by this short, two-week extension. In this lawsuit, Plaintiffs seek to invalidate the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone for medical termination of early pregnancy, which the U.S. Food and Drug Administration (FDA) most recently modified substantively more than four months ago. *See* Compl., ECF No. 1. But Plaintiffs do not seek any preliminary relief from the REMS. To the contrary, they seek preliminary "relief" that would require FDA to *maintain* that REMS. ECF Nos. 8, 10. Plaintiffs identify no agency action that would imminently alter the REMS, and thus have no immediate need for the relief they seek that could be prejudiced by a two-week extension.

4. Based on the irreparable harm section of Plaintiffs' Motion for Preliminary Injunction, *see* Mot. 33-35, ECF No. 10, Defendants anticipate that Plaintiffs will argue Defendants' requested extension will harm them because *another court order* that would

alter the REMS might come into effect – specifically, an April 7, 2023 order entered by the United States District Court for the Northern District of Texas in *Alliance for Hippocratic Medicine, et al. v. FDA, et. Al.*, 2:22-cv-00223-Z (*Alliance Order*), and modified by the United States Court of Appeals by the Fifth Circuit.

5. But the *Alliance Order* does not threaten Plaintiffs with imminent harm, let alone harm that would cause Plaintiffs to be prejudiced by a two-week extension. On April 21, 2023 – upon FDA’s application – the Supreme Court stayed the *Alliance Order* during the pendency of appellate proceedings – including the disposition of any petition for certiorari and any subsequent Supreme Court proceedings if the petition is granted. *Danco Lab’ys, LLC v. All. for Hippocratic Med.*, 143 S. Ct. 1075 (Mem) (2023). The Fifth Circuit will hear oral argument on an appeal from the *Alliance Order* on May 17, 2023, and any petition for a writ of certiorari would be due within ninety days following entry of the Fifth Circuit’s judgment. Per the Supreme Court’s stay decision, the *Alliance Order* would continue to be stayed until the disposition of any timely petition for certiorari, *see* 28 U.S.C. § 2101(c). Moreover, if the government prevails on appeal, the *Alliance Order* will *never* take effect. In any event, given the existing Supreme Court stay, there is no prospect of Plaintiffs being prejudiced by a two-week extension.

6. Finally, Defendants anticipate that Plaintiffs will argue that they are prejudiced because, due to the Court’s schedule, extending Defendants’ time to respond to the Motion for Preliminary Injunction would likely mean that a hearing on that Motion is not scheduled until July. If the Court decides a hearing is required, holding

that hearing in July would not prejudice Plaintiffs. Even if the Fifth Circuit were to decide *Alliance* immediately, and even if that decision were adverse to FDA, the time for filing a petition for certiorari would not run until August at the earliest. There would thus be no prejudice to Plaintiffs were the Court to schedule oral argument for the first or second week of July.

For the foregoing reasons, Defendants respectfully request that the Court, for good cause shown, extend Defendants' time to respond to the Motion for Preliminary Injunction by two weeks, until June 6, 2023.

May 16, 2023

Respectfully submitted,

/s/ Noah T. Katzen

NOAH T. KATZEN

Trial Attorney

Consumer Protection Branch

Civil Division

U.S. Department of Justice

P.O. Box 386

Washington, DC 20044-0386

(202) 305-2428

(202) 514-8742 (fax)

Noah.T.Katzen @usdoj.gov

Certificate of Service

I certify that the foregoing was served on all counsel of record via ECF on May 16, 2023.

/s/ Noah T. Katzen
Noah T. Katzen